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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,486	01/04/2002	Andrew M. Scharenberg	B0662/7026	4102

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WOLF GREENFIELD & SACKS, PC
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON, MA 02210-2211

EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,486	SCHARENBERG, ANDREW M.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,12,34 and 38-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,4,40 and 41* is/are allowed.

6)☒ Claim(s) *34* is/are rejected.

7)☒ Claim(s) *12,38 and 39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 25, 2005 has been entered.

Response to Amendment

2. Claims 1, 12 and 34 have been amended, claims 2-3, 5-11, 13-33 and 35-37 have been canceled and claims 38-41 have been added as requested in the amendment filed on April 25, 2005. Following the amendment, claims 1, 4, 12, 34 and 38-41 are pending in the instant application.

Claims 1, 4, 12, 34 and 38-41 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. The Declaration of Dr. Kinet under 37 CFR 1.132 filed on April 25, 2005 is sufficient to overcome the rejection of claims 1, 4, 12 and 34 based upon 35 U.S.C. 101 and under 35 U.S.C. 112, first paragraph, utility. The Declaration provides additional explanation as well as references to scientific articles published at the time of invention to support the utility of the

claimed nucleic acid molecules encoding SOC-3/CRAC-2 polypeptide of SEQ ID NO: 30 as calcium channel polypeptides useful in regulation of lymphocyte proliferation as originally asserted at page 2 of the instant specification.

6. The Declaration of Dr. Xie under 37 CFR 1.132 filed on April 25, 2005 provides additional data to support the practical utility of the claimed polypeptide of SEQ ID NO: 30 for identification of immunosupressants and, therefore, is sufficient to overcome the rejection of claims under 35 U.S.C. 101/112, first paragraph, utility.

Specification

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 15, lines 12-13, for example). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Applicant is advised to review the entire text of the instant specification for proper use of hyperlinks.

8. It is noted that certain pages of the instant specification (see page 5, for example) contain references to sequences, which are not in compliance with the requirements for Sequence Identifiers (see MPEP 2422.03). The appropriate format for sequence identifiers is SEQ ID NO: X, wherein "X" is the sequence number. Appropriate correction is required.

Claim Objections

9. Claims 12, 34, 38 and 39 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 12 and 34 depend from claim 1, which is limited to a nucleic acid molecule, while claims 12 and 34 encompass polypeptides encoded by that nucleic acid molecule. Therefore, claims 12 and 34 could be infringed by a polypeptide, which does not infringe claim 1. Further, claims 38 and 39 depend from claims 1 and 4, respectively, which are limited to nucleic acid molecule encoding a polypeptide, while claims 12 and 34 encompasses compliments of these molecules, thus making the claims mutually exclusive. Therefore, claims 38 and 39 can be infringed by a nucleic acid, which does not infringe claims 1 and 4. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything, which would not also infringe the basic claim. In the instant case, the polypeptide and complements claims could be infringed without infringing the claims from which it depends, i.e. the coding strand nucleic acid claims. Therefore, they are improperly dependent and should be rewritten in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising a polypeptide of SEQ ID NO: 30, does not reasonably provide enablement for a pharmaceutical composition comprising an isolated nucleic acid molecule encoding a polypeptide of SEQ ID NO: 30. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claim 34 is directed to a pharmaceutical composition comprising an isolated nucleic acid molecule encoding a polypeptide of SEQ ID NO: 30. The presence of limitation "pharmaceutical" is interpreted as intended use of the composition for clinical purposes. The distinguishing property of the instant invention is established based on the asserted utility of polypeptide of SEQ ID NO: 30 as a calcium channel associated with lymphocyte proliferation and regulation of immune response in general. However, the instant specification fails to provide enough guidance for one skilled in the art on how to use the claimed pharmaceutical composition comprising nucleic acid molecules encoding a polypeptide of SEQ ID NO: 30, thereby requiring undue experimentation to discover how to use Applicant's invention, as currently claimed.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

The nature of the invention is the disclosure of a novel calcium channel associated with regulation of lymphocyte proliferation, which can be used to identify agents that modulate immunosupression, for example (see page 2 of the instant specification and also Declarations of Kinet and Xie). However, the instant specification provides no disclosure or working examples on how to use nucleic acid molecules encoding polypeptide of SEQ ID NO: 30 for gene therapy applications, such as in a pharmaceutical composition for treatment of a pathological condition. The state of the art at the time of filing clearly recognizes the high level of unpredictability of any, *in vivo* or *ex vivo*, gene delivery procedures. For example, article by Welsh (Welsh, 1999, Current Opinion in Mol. Therapeutics, 1 (4), pp. 464-470) provides a review of advances in the development of clinically effective gene transfers. It is clear from the publication that at the time of invention the gene therapy approach remained not fully developed with respect to reliable and safe vector delivery systems and was considered risky and generally unpredictable (see p.464 and 467 specifically). Roth et al. provide similar explanation and concerns regarding technical challenges to deliver controlled, therapeutic levels of a gene to a particular cell type to obtain the desired clinical effect stating that "[t]he state of gene therapy was critically evaluated by the National Institute of Health in 1995 [...]. One of primary impediments to successful gene therapy was identified as the low frequency of gene transfer, resulting in insufficient therapeutic benefits" (Roth et al., 1999, Ann. Rev. Biomed. Eng., 01, pp.265-297, specifically page 283).

Therefore, in view of the lack of teachings and unpredictability of the art set forth earlier, and also the total absence of the working examples, the instant specification is not found to be enabling for a pharmaceutical composition comprising an isolated nucleic acid molecule encoding a polypeptide of SEQ ID NO: 30. It would require undue experimentation and making

a substantial inventive contribution for the skilled artisan to discover how to use Applicant's invention as currently claimed.

Conclusion

11. Claims 1, 4, 40 and 41 are allowed. Claims 12, 38 and 39 are objected to, however, would be allowable if rewritten or amended to overcome the objections of record set forth in this Office action. Claim 34 is rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1646

June 4, 2005